IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

No. 02-48V
Filed: March 6, 2014
Not for Publication

SHERYL SCHWARTZ, mother and natural guardian of A.S., a minor,	*	
Petitioner,	*	Fact Ruling; Pervasive Developmental Disorder; PDD; Autism; Autism Spectrum Disorder; ASD; Statute of Limitations.
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Clifford J. Shoemaker, Esq., Shoemaker and Associates, Vienna, VA, for petitioner.
Traci R. Patton, Esq., United States Dep't of Justice, Washington, DC, for respondent.

FACT RULING[1]

Vowell, Chief Special Master:

On January 17, 2002, Sheryl Schwartz ["petitioner"] filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] [the "Vaccine Act" or "Program"], on behalf of her minor son, AS. Petitioner alleges that as a result of several vaccines, AS suffered a "toxic encephalopathy" and autism. The following ruling resolves several disputed issues of fact which have arisen during the course of proceedings.

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[1] Because this ruling contains a reasoned explanation for my action in this case, it will be publically available in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire ruling will be available to the public.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

I. Procedural History.

In her initial petition, filed on January 17, 2002, Ms. Schwartz alleged that as a direct result of one or more thimerosal containing vaccines, AS developed autism. Petition at ¶ 8. AS's case was thus included in the Omnibus Autism Proceeding ["OAP"] and proceedings were stayed. Notice Regarding "Omnibus Autism Proceeding," issued July 15, 2002.

The OAP was created to resolve what ultimately totaled about 5,700 petitions alleging that vaccines or the thimerosal preservative contained in some vaccines caused ASD. In an omnibus proceeding, test cases are selected for hearings in which the parties present evidence generally applicable to the cases in the omnibus proceeding, as well as evidence specific to the test cases. The results in the test cases are not binding on anyone other than the test case petitioners, but the body of evidence created can be used to resolve the remaining cases.

In the OAP, three test cases[3] were selected for each of the two theories of vaccine causation advanced by the petitioners' bar. Hearings in the test cases were conducted in 2007 and 2008, and decisions issued in 2009 and 2010. The decisions in the Theory 1 test cases (which advanced the theory that the measles, mumps, and rubella ["MMR"] vaccine, either alone or in concert with thimerosal-containing vaccines caused autism) were appealed; the decisions in the Theory 2 test cases (which alleged that thimerosal-containing vaccines caused autism) were not appealed.

After the conclusion of the appellate process in the OAP test cases, petitioner filed an amended petition ["Am. Pet."] on July 12, 2011, claiming AS's December 8, 1998 and April 8, 1999 vaccinations caused mercury poisoning and toxic encephalopathy.[4] Am. Pet. at ¶¶ 7, 9, 12.

On September 20, 2011, the special master formerly assigned to this case[5] ordered petitioner to show cause why the case should not be dismissed based on the

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[3] The OAP test cases are discussed in more detail in *Dwyer v. Sec', HHS*, No. 03-1202V, 2010 WL 892250, at *3 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

[4] Petitioner does not claim that AS suffered the Table Injury of encephalopathy. *See* 42 C.F.R. § 100.3 (2011). Rather, petitioner claims that the vaccines caused mercury poisoning and encephalopathy, leading to the development of AS's autism symptoms. Am. Pet. at ¶¶ 10, 12.

[5] This case was reassigned to me on March 8, 2013.

evidence adduced during the OAP. Order at 1-3. The special master explained that the mercury toxicity theory set forth in the amended petition was rejected in the OAP test cases.[6] Order at 1. The special master also noted that the symptoms of AS's developmental delay appeared to predate the administration of the allegedly causal vaccines on December 8, 1998 and April 8, 1999. *Id.* at 2.

On January 19, 2012, petitioner filed a response arguing that petitioner's mercury toxicity theory was still viable, based on new evidence not considered in the OAP test cases. Petitioner's Response to Show Cause Order at 1-2. Petitioner maintained that AS did not have any autism related symptoms prior to his receipt of the December 1998 and April 1999 vaccinations. *Id.* at 5-6.

During an October 10, 2012 status conference, respondent observed that the petition may not have been timely filed. Petitioner's counsel responded that he intended to rely on an equitable tolling of the statute of limitations. The parties agreed it would be helpful to clarify the facts before moving forward with expert testimony. *See* Order, issued Oct. 12, 2012. Petitioner was therefore ordered to file proposed findings of fact, an affidavit from every fact witness on whose testimony petitioner intended to rely, and any additional medical records supporting the factual findings. Petitioner was also ordered to support each proposed finding of fact with specific citations to AS's medical records or filed affidavits. Respondent was likewise ordered to submit proposed findings of fact. Order, issued Oct. 12, 2012.

Petitioner's proposed findings of fact were filed on December 12, 2012, and respondent's proposed findings of fact were filed on March 12, 2013. A subsequent filing by petitioner clarified the remaining areas of disagreement. Petitioner's Response to Respondent's Proposed Findings of Fact, filed Apr. 2, 2013.[7]

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[6] *See Dwyer,* 2010 WL 892250; *King v. Sec'y, HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y, HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

[7] The parties' primary disagreements involved: the nature of Ms. Schwartz's concerns when AS was 14 months old, around December 1998; the purpose of AS's speech therapy evaluation in early 1999; the consistency of the results of the developmental evaluations conducted in January 1999 (before the allegedly causal vaccinations) and October 1999 (after those vaccinations); and whether AS was exhibiting speech delay prior to his April 1999 vaccinations. *Compare* Respondent's Proposed Findings of Fact ["Res. Proposed Findings of Fact"], *with* Petitioner's Response to Respondent's Proposed Findings of Fact ["Pet. Resp. to Res. Proposed Findings of Fact"].

In an April 10, 2013 status conference, petitioner's counsel requested that I hear testimony from AS's parents before ruling on the remaining factual disputes. *See* Order, issued Apr. 12, 2013, at 1. I therefore set a fact hearing for August 16, 2013. Pre-Hearing Order, issued May 30, 2013.

Prior to the scheduled hearing, petitioner moved for a fact decision on the record. Motion for Fact Decision on the Record, filed July 22, 2013. At a status conference on July 30, 2013, held to clarify petitioner's intentions, the parties agreed to waive any fact hearing, and to permit me to resolve controverted factual issues based on the record as a whole. *See* Order, issued July 30, 2013.

II. Relevant Medical History and Factual Findings.

A. Relevant Medical History.

1. Well and Sick Child Visits Through January 1999.

AS was a full-term, healthy baby at birth on October 7, 1997, with Apgar scores of 9 and 10.[8] Pet. Exs. 8, p. 6; 17, p. 7. On October 11, 1997, AS was seen for his initial well child checkup. Pet. Ex. 18, p. 21. He received his first hepatitis B vaccination during this visit. *Id*., pp. 2, 21.

On November 6, 1997, Ms. Schwartz called AS's pediatrician to report that AS had congestion and received advice about how to treat it. Pet. Ex. 18, p. 21. Four days later, on November 10, 1997, AS was seen for his one-month well child checkup. Ms. Schwartz again expressed concern about AS's congestion and apparently related the congestion to his initial vaccination, as AS's pediatrician drew an arrow in the medical record toward the word "shots" after noting her concern. AS met all developmental milestones at this visit, with the possible exception of "coos, small noises," next to which the doctor noted "+/-." *Id.*, p. 20. During this visit, AS received his second dose of the hepatitis B vaccine. *Id.*, pp. 2, 20.

[8] The Apgar score is a numerical assessment of a newborn's condition (with lower numbers indicating problems), usually taken at one minute and five minutes after birth. The score is derived from the infant's heart rate, respiration, muscle tone, reflex irritability, and color, with from zero to two points awarded in each of the five categories. *See* DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ["DORLAND'S"] (32d ed. 2012) at 1682.

AS's congestion had resolved by his two-month well child checkup on December 11, 1997. Pet. Ex. 18, p. 20 (noting no parental concerns). He received his first diphtheria, tetanus, and acellular pertussis ["DTaP"] and haemophilus influenzae type b ["Hib"] vaccinations at this visit. *Id.*, p. 2. On January 13, 1998, AS received his first dose of the inactivated polio vaccine ["IPV"]. *Id.* It does not appear that any office visit occurred in conjunction with the IPV vaccination. *See generally id*.

Ms. Schwartz reported no acute concerns at AS's four-month well child visit on February 9, 1998, except that AS was "still spitting up" and woke at night. AS met each developmental milestone, including "vocalizes" and "reaches for objects with both hands." Pet. Ex. 18, p. 19. During this visit, AS received his second DTaP and Hib vaccinations. *Id.*, pp. 2, 19.

On March 9, 1998, at five months of age, AS was seen for what was listed as his six-month well child checkup. Ms. Schwarz was concerned that AS was spitting up frequently after feeding and was only eating a few bites of food. AS woke three to four times a night, wanting to be fed. He also had frequent loose stools. The doctor noted that AS was suffering from reflux and recommended cereal with soy, but decided to "hold off reflux meds." AS met some of the six-month developmental milestones, including "babbles frequently," "reaches with both hands," and "works for objects out of reach," but others were unchecked, and "not yet" was written above "sits alone" and "sits tripod." Pet. Ex. 18, p. 18. During this visit, he received his second IPV vaccination. *Id.*, pp. 2, 18. A follow up appointment was recommended in three to four weeks (*id.*, p. 18), but there is no record of a follow up visit in April 1998 (*see generally id.*).

In early May 1998, AS suffered from symptoms of croup, including a barking cough and stridor. Despite his illness, AS was described as "happy and social" and alert, smiling, and in good spirits. Pet. Ex. 18, p. 17.

AS had his nine-month well child checkup on July 7, 1998. Ms. Schwartz's only concern was his resistance to bottle feeding. AS's pediatrician discussed feeding issues and instructed Ms. Schwartz to "encourage formula." He also made a notation to "follow weight gain closely." On a developmental screen, AS received a checkmark for each milestone, except for "cruises," for which "+/-" was noted. He imitated speech sounds and enjoyed playing patty cake. Pet. Ex. 18, p. 16. AS received his third hepatitis B vaccination during this visit. *Id.*, pp. 2, 16.

On December 8, 1998, AS, then 14 months of age, had his one-year well child checkup. Ms. Schwartz's only reported concern was that AS would vomit after stage 3 solids and had "trouble [with] texture." AS had particular trouble with eating whole

grains, fruits, vegetables, and meats. AS's developmental examination was significant for questions about his ability to communicate. A question mark was written next to the developmental milestones "indicates wants (without crying)" and uses "'dada & mama' specific." Additionally, the milestone "3 other words" was marked with a "2," indicating that AS had two words other than "dada" and "mama." It appears that AS's pediatrician referred him for an "evaluation by speech/OT"[9] but parts of the handwritten note regarding this referral are cut off on the copied page. Pet. Ex. 18, p. 15. AS received his first MMR vaccination and his third DTaP vaccination during this visit. *Id.*, pp. 2, 15. These two vaccinations are among those petitioner claims are causal of AS's condition.

On December 9, 1998, the day after his one-year well child check, AS had a temperature of 102° Fahrenheit and his left thigh was soft without redness. Pet. Ex. 18, p. 14.[10] Ms. Schwartz was advised to give AS Motrin and call if his condition worsened. *Id.* There is no medical record indicating any follow up call was made.

AS next returned to his pediatrician nearly a month later, January 6, 1999, for a burn on his hand. Pet. Ex. 18, p. 14. He had follow up appointments for his burn on January 7, 8, and 13, 1999. *Id.*, p. 13.

2. Initial Early Intervention Evaluation.

On January 19, 1999, AS, then 15 months old, had a multidisciplinary early intervention evaluation due to concerns about his feeding.[11] Pet. Ex. 16, p. 24. He was referred for this evaluation by his pediatrician on December 10, 1998. Pet. Ex. 23, pp. 14-15. In a part of the intake form for parental concerns, Ms. Schwartz commented that she "was not all that concern[ed] until Dr. recommended speech therapy." Ms.

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[9] "OT" likely refers to occupational therapy. *See* N. Davis, *Medical Abbreviations* (15th ed. 2011) [herein after "*Medical Abbreviations*"], at 242.

[10] In her proposed findings of facts, respondent interprets Pet. Ex. 18, p. 14 to read "with redness." Res. Proposed Findings of Fact at ¶ 12; *see also* Pet. Resp. to Res. Proposed Findings of Fact at 1 (agreeing with respondent's interpretation). The abbreviation used in the medical record is clearly an "s" with a horizontal line above it. This abbreviation means "without," however it is regarded as "a dangerous abbreviation," likely because of the possibility of being interpreted as "with," which is abbreviated using a "c" with a horizontal line over it. *Medical Abbreviations* at 68, 289.

[11] I note that the family concerns and priorities listed were "speech development and eating." They wanted AS "to be open and accepting different textures and different foods" and "to be able to express himself verbally." Pet. Ex. 16, p. 47.

Schwartz wanted to make sure she was doing what was needed to help AS eat solid food. *Id.*, p. 14.

The evaluation, led by a team from the Northern Virginia IDEA Center ["IDEA Center"], was conducted in Ms. Schwartz's home. Pet. Ex. 16, pp. 24-25. The evaluators concluded that that AS had an aversion to textured foods and showed signs of decreased oral sensation, which he compensated for by "excessively mouthing toys and objects." *Id.*, p. 27. They assessed AS as:

> showing skills at 12-14 months in gross motor development, 12-14 months in fine motor development , 10-12 months in self help development, 11 months in cognition with scattered skills up to 15 months, 12-15 months in social-emotional development, 12 months in receptive language development, 9 months in expressive language development with scattered skills up to 12 months, and atypical oral-motor development.

Id.

Specific findings of relevance to the issues presented in this case include an observation that AS was mouthing toys. Pet. Ex. 16, p. 26. He appeared to be "visually attentive to the details on objects and liked to turn objects around and look at all aspects of them." He was observed to say "uh-oh" and to wave "bye-bye." He used the vocalization "dada" with strong inflection consistently to call his sister. AS was not yet pointing and communicated his needs primarily by crying. He used "gestures to initiate interaction as well as to request continuation of a game," but he did not respond to commands made without gestures. *Id.* He displayed "nice eye contact" in interacting with others. *Id*. There was no indication that these communication problems were of sudden or recent origin.

Areas of concern noted were the amount of functional and pretend play; AS's limited use of consonant sounds; his failure to use a "'true' word" or to identify body parts; his inability to respond to requests without a gesture; limited ability to move his tongue effectively; and possible decreased sensation in his mouth, resulting in drooling and decreased tone. Pet. Ex. 16, p. 46.

Goals were established for both eating and speech development. His speech goal was to "indicate his wants and needs verbally." Pet. Ex. 16, p. 50. Specific activities and strategies to reach this goal included requiring AS to make choices with gestures or gaze, use specific words, perform kissing exercises, and use gestures to help develop speech. *Id*.

Due to "a 25% delay in cognitive development, expressive language development, self help, and atypical oral-motor development," AS was eligible for early intervention services. Pet. Ex. 16, p. 28. He was assessed with developmental delays in cognition, communication, and adaptive behavior. Pet. Ex. 23, p. 19. According to his pediatric records, AS began therapy for speech delay on February 11, 1999. Pet. Ex. 18, p. 13.

On March 15, 1999, he was discharged from speech therapy at the family's request due to their comfort with implementing the recommendations of the therapist on their own. Pet. Ex. 23, pp. 11-12. The speech therapy discharge summary indicated that at the time therapy began, AS produced few consonants, followed directions inconsistently, and had limited functional pretend play. *Id.*, p. 12. At the time of his discharge, AS was "eating solids such as apples," imitating speech, speaking six to ten words, and responding to verbal, visual, and touch cues.[12] Pet. Ex. 23, p. 12. Nevertheless, Ms. Schwartz was advised to monitor AS's cognitive and social/emotional development, increase variety of functional and pretend play, continue intensive speech therapy "for probable verbal dyspraxia,"[13] and to monitor AS's hearing. Pet. Ex. 23, p. 12. AS's hearing was tested on March 24, 1999, and found to be "within normal limits." Pet. Ex. 16, p. 29.

3. April-June 1999 Pediatric Visits.

On April 8, 1999, AS was seen for his 18-month well child checkup.[14] Pet. Ex. 18, p. 12. AS's doctor recorded that speech therapy was helping with his problem with textures. During a developmental assessment, the doctor noted that AS was imitating housework, using a spoon, stacking two cubes, walking, and throwing a ball. AS, however, was not scribbling. Additionally, the doctor noted "+/-" for both "3 other words than 'mama, dada'" and "points to one body part." The doctor also included a note to "watch speech," and indicated that follow up appointments should be scheduled in one and six months. She also diagnosed left otitis media (ear infection). *Id.* During this

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[12] Although AS's name appears at the top of the discharge summary, the therapist erroneously referred to him as "Michael" in her handwritten comments. Pet. Ex. 23, p. 12.

[13] "Dyspraxia" is the "partial loss of ability to perform coordinated acts." DORLAND'S at 582.

[14] In her proposed findings of fact, respondent notes that AS's pediatric records contain no evidence that he had a 15-month well child check. Res. Proposed Findings of Fact at ¶ 14; *see also* Pet. Resp. to Res. Proposed Findings of Fact at 2 (agreeing that AS did not have a 15-month visit).

visit, AS received his first combined DTaP/Hib vaccination and his third IPV vaccination (*id.*, pp. 2, 12), the second set of vaccinations that petitioner identifies as causing AS's condition.

A note from April 15, 1999, indicated that a nurse in the pediatric practice talked with someone about AS still pulling on his ears. Pet. Ex. 18, p. 12. At a followup visit for the ear infection on April 28, 1999, after completion of a course of antibiotics, AS had mild bilateral otitis media. *Id.* On June 10, 1999, he was seen for a rash and was diagnosed with hand, foot, and mouth disease. *Id.*, p. 11.

4. July 1999 Report of Regression and Subsequent Referrals.

On July 8, 1999, Ms. Schwartz took AS, then 21 months of age, to his pediatrician, complaining of fussiness, sleeping problems, "not speaking clearly," and possible loss of words. Pet. Ex. 18, p. 11. The physician noted that AS had "[s]ome recent speech regression" and was "[n]ot responding." The doctor diagnosed AS with an ear infection, upper respiratory infection, and behavioral issues. Ms. Schwartz was advised that AS "may need to see 'Child-Find' if developmental issues persist." *Id.*

AS was seen again on July 21, 1999, for followup of his ear infection. He was still fussy and still pulling at his ears, and had developed a rash. He was prescribed antibiotics for the ear infection, and Benadryl for the rash. The doctor recommended that AS be evaluated for developmental issues and possible PDD.[15] Pet. Ex. 18, p. 10.

5. Fairfax County School Evaluation.

On July 23, 1999, AS was evaluated by Fairfax County Public Schools ["FCPS"] Department of Student Services and Special Education. Pet. Ex. 16, p. 7. Ms. Schwartz reported that AS had "regressed in language," adding that he "no longer says

[15] Pervasive Developmental Disorder ["PDD"] was the umbrella term for ASDs used in the Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association, 4th ed. text revision 2000) ["DSM-IV-TR"] at 69. The DSM-IV-TR has since been replaced by the Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association, 5th ed. 2013) ["DSM-V"], which uses the term "autism spectrum disorder." The DSM-IV-TR was in use at the time of AS's referral. *See White v. Sec'y, HHS*, No. 04-337V, 2011 WL 6176064, at *6 (Fed. Cl. Spec. Mstr. Nov. 22, 2011) (discussing the DSM-IV-TR and its definition of PDD).

any words vs. the 5-6 he use[d] to say at 18 months." *Id.* Based on significant problems on the developmental screening, more formal evaluations (psychological, sociocultural, educational, speech/language, and hearing) were recommended. *Id*. On July 30, 1999, Ms. Schwartz gave permission for these evaluations to be performed. *Id*., p. 9.

6. Early Intervention Review in July 1999.

In an Early Intervention Services six-month review, performed on July 26, 1999 (Pet. Ex. 16, p. 31), Ms. Schwartz reported that AS "had made progress (and was using some words), but he is no longer using words he had." She added that "[h]e does babble frequently." At this time, AS's eating was "going very well," and he was no longer a picky eater. *Id.*, p. 32. The family was concerned that his series of recent ear infections was impacting his speech development, and making him more irritable, cranky, and frustrated. *Id.*, p. 33. They decided to hold off on the testing recommended by FCPS until his ear infections had resolved. *Id.*, p. 35. Ms. Schwartz expressed some ambivalence about the decision to hold off on testing, asking if she was "in denial" about AS's problems, and indicating that it was "disheartening" to be told her child was developmentally delayed. Pet. Ex. 23, pp. 148-49.

7. July 30, 1999 Pediatric Visit.

AS returned to his pediatrician on July 30, 1999. Pet. Ex. 18, p. 10. The pediatrician recorded that AS had been "more irritable over past 2 mos. [with] regression of speech." AS had undergone an evaluation by Child Find and needed further evaluation due to developmental delays in social, speech, and fine motor skills. During the examination, AS was uncooperative and screaming. The assessment was speech regression and social delay, and questionable PDD. The doctor recommended that AS proceed with the autism/PDD evaluation and continue the Child Find evaluation. *Id*.

8. Reevaluation by FCPS.

On October 13 and 20, 1999, AS was evaluated again by a FCPS Interdisciplinary Team. Pet. Ex. 16, p. 12. Ms. Schwartz reported that AS "had some feeding problems which were evident at 14 months when he gagged easily on solid food and would only eat pureed foods." *Id.*, p. 13. She also reported that AS was using only two words, "hi" and "bye-bye," and the exclamation, "uh-oh." *Id.*, pp. 13, 16. AS used gestures such as pointing or pulling a parent towards a desired object when he wanted something. *Id.*, pp. 13, 16, 19. Ms. Schwartz reported that "at 13-15 months of age, [AS] had several words in his vocabulary and would repeat short phrases," but by 18 months, he "stopped talking altogether." Ms. Schwartz felt that, besides his language

delays, AS was developing normally. *Id.*, p. 13. She conveyed that he was making good eye contact, would approach a parent with vocalizations, and would initiate affection. *Id.*, pp. 13, 15.

AS had problems with transitions from a favored activity, responding with tantrums. Pet. Ex. 16, p. 15. He made brief eye contact with the examiners. He engaged in repetitive and self-directed behaviors and had difficulty focus on the testing activities. *Id.* Ms. Schwartz reported that AS understood about 20 words and only sometimes responded to his name. *Id.*, pp. 16, 19. He did not point to pictures and, although able to recite all the letters of the alphabet, he would respond to questions or activities with random sequences of letters. He did not imitate words. *Id.*, p. 16. AS could not point to one body part. He mouthed objects. *Id*., p. 17.

Summarizing their evaluation, the multidisciplinary team noted that AS's "[c]urrent overall cognitive functioning was assessed at 12 months," adding, however, that the results "are interpreted cautiously considering his young age and language delays, and behavior during testing." Pet. Ex. 16, p. 20. Ultimately, they concluded that AS's receptive and expressive language skills were clustered at the 8-month level, constituting a severe delay; his fine motor skills were at the 12-month level, constituting a significant delay; he had a variable attention span, sometimes over focused, demonstrated repetitive behaviors, and mouthed and threw objects; and his self-help skills were delayed. *Id.*, p. 20.

On November 4, 1999, AS was declared eligible for special education. Pet. Ex. 22, p. 159.

9. Two-Year Well Child Visit.

On November 10, 1999, AS returned to his pediatrician for his two-year well child checkup. Pet. Ex. 18, p. 8. Ms. Schwartz reported a possible PDD diagnosis, and that AS was to see a neurologist. She also reported that AS loved routine and had "poor speech." The doctor found AS to be a "well toddler [with] developmental delay" and referred him to a neurologist. The varicella vaccine was discussed but was deferred. *Id*.

10. Neurologist Visit.

AS was seen by pediatric neurologist Terry Watkin on November 17, 1999. Pet. Ex. 15, pp. 34-35. One of the forms in Dr. Watkin's records (which is undated) indicates that the consultation was undertaken to obtain a diagnosis of autism, rather than PDD, in order to obtain school system services. *Id.*, p. 20; *see also id.*, p. 22. At the initial

visit, Ms. Schwartz reported that she "first had concerns when [AS] was 14 months of age when he still was having problems and was only able to eat purees," adding that AS "had trouble with any solids and began to vomit and gag."[16] Pet. Ex. 15, p. 34. Concerning AS's speech problems, Ms. Schwartz reported that she had concerns when he was 16 to 18 months old. "At that point he had a number of words and was very verbal. He was using them appropriately. He suddenly stopped using all words for a couple of months and now has a couple of words." Ms. Schwartz also reported that he had good eye contact "when he wants to," "a limited repertoire of play," selective play interests, engages primarily in parallel play, and flaps and waves when frustrated. *Id.*

Doctor Watkin found AS's general medical and neurologic exam to be notable for mild hypotonia. He added that AS would not make eye contact with him and did not like being touched. He concluded that "there is little doubt that [AS] has pervasive developmental disorder versus an acquired epileptic aphasia." Pet. Ex. 15, p. 34. Dr. Watkin referred AS for an EEG,[17] noting that "[i]f this is normal then I think there is little doubt about the diagnosis." Pet. Ex. 15, pp. 34-35. An EEG, performed on December 9, 1999, was normal. *Id.*, p. 23. Therefore, Dr. Watkin concluded that there was "little doubt" that AS had pervasive developmental delay/autism spectrum disorder. *Id.*, p. 22.

11. Children's National Medical Center ["CNMC"] Evaluation.

On April 21, 2000, AS, then 30 months of age, was seen at CNMC by developmental psychologist Penny Glass (PhD) for a developmental evaluation. Pet. Ex. 6, pp. 5-7. In summarizing AS's history, she recorded that around 14 months of age, AS's social communication skills were typical as he would wave goodbye, throw kisses, sing along with "Ole MacDonald," and utter "uh-oh" appropriately and "dada," but nonspecifically. *Id.*, p. 5. She added that "[a]round 18 months this behavior stopped in

[16] In her response to respondent's proposed findings of fact, petitioner states that Dr. Watkin's letter reflects that the problems AS had at 14 months of age were related to his feeding and texture aversion, not his speech problems. Pet. Resp. to Res. Proposed Findings of Fact at 2; *see also* Pet. Ex. 16, p. 13. I agree with petitioner that this is what Dr. Watkin wrote, but, as noted in Pet. Ex. 18, p. 15, the initial referral for early intervention services was also based on speech and language delays, not just feeding issues.

[17] "The EEG is a graphic recording of the electrical activity of the brain." MOSBY'S MANUAL OF DIAGNOSTIC AND LABORATORY TESTS (4th ed. 2010) at 573.

an apparent regression" (*id*.), and noted later in her report that AS's "language was not normal prior to [the time of the apparent regression]"[18] (Pet. Ex. 6, p. 6).

Although additional medical records were filed, the matters in controversy are not further elucidated in those records.

B. Factual Findings.

1. AS had issues with feeding beginning very early in infancy. He had reflux before four months of age. He would only eat a few bites of solids at five months of age. He was resistant to bottle feeding at nine months of age, and his physician had concerns about his weight gain at that point. By 14 months of age, AS's was having difficulty eating solid foods and foods with texture.

2. AS's development was normal before 12 months of age. Although there were some skills that AS had not mastered at the time of several well-child visits before this time, there were no recorded concerns about developmental delays.

3. By 14 months of age and thereafter, AS's social communication skills were not normal. At a well child visit in December 1998, when AS was 14 months of age, his pediatrician first noted concerns about his communication skills. AS was not using the terms "mama" and "dada" to refer to specific people, and he indicated his wants and needs by crying. He did not use three words other than "mama" and "dada." These concerns, along with the feeding concerns, prompted an early evaluation referral.

4. AS received the first set of allegedly causal vaccinations at this well child visit. Although AS ran a fever the day after his December 1998 vaccinations, there is no record of any follow-up treatment for the fever. There was redness, but no hardness, at the injection site.

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[18] In her response to respondent's proposed findings of fact, petitioner acknowledges Dr. Glass's statement about AS's language prior to 18 months, but notes that Dr. Glass also referred to AS's speech therapy at around 12 months of age because of his gagging and that and his "typical" social skills around 14 months of age. Petitioner's Response to Respondent's Proposed Findings of Fact at 2 (citing Pet. Ex. 6, p. 5). Again, this represents a history provided by petitioner and not the specific areas of concern identified by Ms. Schwartz at the time of the speech therapy or the findings by the evaluation team regarding communication delays.

5. At this well child visit, the pediatrician referred AS for a speech and occupational therapy evaluation. That multidisciplinary evaluation took place on January 19, 1999.

a. Although the initial page of the evaluation report listed the reason for the evaluation as concerns about feeding, I find that the evaluation was also conducted because of concerns about AS's communication skills. I base this finding on the pediatrician's recorded concern about speech at the time of the referral and the nature of the evaluation conducted, which included testing AS's expressive and receptive language. I also base this finding on the parental concerns section of the intake form, in which Ms. Schwartz indicated that her concern about AS was heightened when AS's doctor recommended speech therapy. Additionally, goals were established for speech development, and the 25% delay in expressive language development identified was part of the basis for AS's eligibility for early intervention services.

b. This multidisciplinary evaluation found that AS engaged in excessive mouthing of toys and other objects, was visually attentive to the details of objects, turned objects around to look at all aspects of them, used only two discernible words, used the term "dada" to call his sister, did not point, and communicated his needs primarily by crying. He did not respond to commands made without gestures. Although he was 15 months of age at the time of the evaluation, his receptive language skills were scored at the 12 month level, and his expressive language skills were scored at the nine month level.

c. AS's functional and pretend play skills were an area of concern. Additionally, AS could not identify body parts.

d. AS was assessed as developmentally delayed in three areas: cognition, communication, and adaptive behavior. Although AS clearly had problems with feeding, textures, limited ability to move his tongue effectively, and possible decreased sensation in his mouth, the goals established for therapy after the evaluation appeared to focus on speech and communication as much or more than feeding skills.

6. AS attended speech therapy for slightly more than one month before being discharged from therapy at his family's request. He still displayed problems with speech production, communication, and functional pretend play when discharged from speech therapy. His vocabulary had improved to six to ten words. He was able to imitate two-word phrases. Nevertheless, the therapist recommended continuing intensive speech therapy.

7. AS's gains in vocabulary during his month in speech therapy were short-lived. Prior to the second set of allegedly causal vaccinations, at his 18-month well child checkup in April 1999, once again, it was questionable whether AS had three words other than "mama" and "dada." It was also questionable whether AS could point to one body part. The physician was concerned enough to record "watch speech" and recommended follow-up appointments in one and six months. No specific follow-up appointments were made. AS received the second set of allegedly causal vaccinations at this visit (a combined DTaP/Hib and IPV vaccinations).

8. AS's next pediatric visits were for illness. The two April 1999 consultations following his well child checkup concerned problems with ear infections. In June 1999, AS was diagnosed with hand, foot, and mouth disease.

9. At a July 8, 1999 pediatric visit, Ms. Schwartz complained of AS's fussiness, sleeping problems, problems with intelligibility of speech, and possible loss of words. Based on the physician's notation about lack of responsiveness, I conclude that AS was also having problems with receptive language. The physician assessed AS with developmental problems. At a follow-up visit two weeks later, the physician recommended an evaluation for developmental issues and possible PDD.

10. A preliminary evaluation by FCPS took place on July 23, 1999. Ms. Schwartz reported that AS's speech had regressed from five to six words spoken at 18 months of age to none at the time of the evaluation. Based on the developmental screening, more formal evaluations were recommended, and Ms. Schwartz gave permission for those evaluations to be performed. However, the family decided to delay testing until AS's ear infections had resolved. Therefore, this testing was not completed until October 1999.

11. Early intervention services conducted a review of AS's progress in July 1999, just three days after the preliminary evaluation by FCPS. I interpret Ms. Schwartz's report as indicating that AS had made progress in speech during the period of speech therapy, but had subsequently lost the use of words that he had previously exhibited. The family attributed AS's loss of speech and some problems with behavior, which included irritability and frustration, to his several ear infections between April and July 1999.

12. The FCPS evaluation took place on October 13 and 20, 1999. I find significant similarities between AS's performance at this evaluation and the January 1999 early intervention evaluation.

a. AS displayed behaviors consistent with an autism spectrum disorder at the time of his initial early intervention examination in January 1999. All of these behaviors were most likely present at the time of the first set of allegedly causal vaccinations, but the communication problems certainly were. AS's expressive speech was delayed more than his receptive communication ability, but there were delays in both. He focused on the details of toys and other objects, turning them around to fully observe them. He communicated wants and needs by crying or by taking a parent to the desired object. There were delays in functional and pretend play. He could not identify one body part. He mouthed objects. However, he made eye contact when interacting with others.

b. Although AS made some gains in vocabulary during the month of speech therapy from February to March, 1999, it is unclear whether this represented the spontaneous use of words or imitating speech, as seen in echolalia, a symptom often associated with autism spectrum disorders. He used short phrases only in imitation. Other communication difficulties and other behaviors associated with autism spectrum behaviors persisted at the time of discharge from speech therapy. He followed directions inconsistently, and had limited functional and pretend play. There were unspecified concerns about AS's social and emotional development as well, given the recommendation to "monitor" his development in these areas.

c. AS displayed similar delays at the FCPS evaluations in October 1999. AS was using only two words, and the exclamation, "uh-oh," approximately the same level of vocabulary as at the January 1999 evaluation. Testing showed that his expressive language skills were at the eight-month level, similar to the finding of expressive language skills at the nine-month level during the January 1999 evaluation. He was still pulling a parent to objects he desired. Although it was reported that AS had used several words and would repeat short phrases at 13-15 months of age, the contemporaneous evaluations during those periods did not reflect whether words were used spontaneously, and the speech therapy records reflect that the use of short phrases was used in imitation. Just as at the January 1999 evaluation, AS over-focused on and mouthed objects. He still could not point to one body part.

d. AS had two words and one exclamation at 14-15 months of age. During his month in speech therapy, he used six to ten words, but shortly after ceasing speech therapy he no longer used those words. By October 1999, when he was two years old, AS still had only two words, and one exclamation. He could recite the alphabet, and appeared to use random letters or consecutive alphabet letters in response to questions.

e. AS displayed less eye contact at the October 1999 examination than he did at the January 1999 evaluation.

13. In response to the areas of conflict identified by the parties, I explicitly find:

a. The January 1999 referral was made both because of AS's feeding difficulties and his language delays. The brief period of therapy that ensued focused on both feeding and speech issues.

b. In mid-March 1999, at the time of discharge from speech therapy at his parents' request, AS had made brief gains in vocabulary. Precisely when AS lost these words is impossible to determine, but the loss of these words and the two words used prior to beginning speech therapy had occurred by the time of his July 1999 pediatric visit. At this visit, AS was not using words. However, he had regained the use of two words and one exclamation by the time of his October 1999 FCPS evaluation. I make no finding regarding whether this represented a speech regression; based on evidence presented in the OAP and other cases, I believe expert testimony is necessary to make this determination.

c. There were few differences between AS's behavior and attainments at the January 1999 early intervention evaluation and the October 1999 FCPS evaluation. His eye contact had worsened, but most of the other findings were strikingly similar to those displayed at the January 1999 evaluation. Although the October 1999 evaluation was more comprehensive, I note that AS was older, and thus more capable of performing specific testing tasks. Nevertheless, the findings of delays in communication were almost identical (expressive language at an eight month versus a nine month level).

III. Orders to the Parties.

The onset of what was ultimately diagnosed as an autism spectrum disorder appears to have arisen more than 36 months prior to the filing of the original petition in this case, and thus this case is likely time-barred. If respondent desires to file a motion to dismiss based on untimely filing, she shall file such motion by no later than **Tuesday, May 6, 2014**, identifying with specificity the behaviors constituting symptoms of an autism spectrum disorder upon which she relies and evidence establishing that these behaviors constitute symptoms of an autism spectrum disorder.

If expert reports are produced, either as a part of the evaluation of timely filing or on the issue of causation, the parties are directed to provide a copy of these factual findings to their respective experts. The experts shall conform their expert opinions to

these factual findings. Should an expert disagree with any factual finding herein, that expert shall clearly state in a supplemental report: (1) the finding involved; (2) the reasons for the expert's disagreement; and (3) the impact, if any of my contrary finding on the expert's conclusions regarding causation. If needed, a schedule for the production of expert reports will be set forth in a future order.

IT IS SO ORDERED.

s/Denise K. Vowell
Denise K. Vowell
Chief Special Master